

# PATENT COOPERATION TREATY

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From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

## PCT

To:

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27. April 2004

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT  
(PCT Rule 71.1)

Date of mailing  
(day/month/year) 26.04.2004

Applicant's or agent's file reference  
02/003 LTS

### IMPORTANT NOTIFICATION

International application No.  
PCT/EP 03/00334

International filing date (day/month/year)  
15.01.2003

Priority date (day/month/year)  
25.01.2002

Applicant  
LTS LOHMANN THERAPIE-SYSTEME AG et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international  
preliminary examining authority:



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PATENT COOPERATION TREATY

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# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 02/003 LTS	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP 03/00334	International filing date (day/month/year) 15.01.2003	Priority date (day/month/year) 25.01.2002
International Patent Classification (IPC) or both national classification and IPC A61K9/70, A61K9/70		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.  
  
☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
  
 These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  12.08.2003	Date of completion of this report  26.04.2004
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Luangkhot, N  Telephone No. +49 89 2399-7857

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/EP 03/00334**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1, 3-7	as originally filed
2, 2a	filed with telefax on 13.04.2004

**Claims, Numbers**

8-15	as originally filed
1-7, 16-18	filed with telefax on 13.04.2004

**Drawings, Sheets**

1/1	as originally filed
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2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/EP 03/00334**

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-18
	No: Claims	
Inventive step (IS)	Yes: Claims	1-18
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-18
	No: Claims	

2. Citations and explanations

**see separate sheet**

**Re Item I**

**Basis of the opinion**

New amended claims 1 and 17 are allowable according to Article 34(2)(b) PCT because a support was found in the description and these amendments do not introduce subject-matter which extends beyond the content of the application as filed. These amendments permit to overcome the clarity objection raised in the written opinion.

**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

- 1) The documents cited in the International Search Report (ISR) were numbered respectively from D1-D5; this numbering results from the citation order in the ISR and will be used for the procedure. Unless otherwise specified, the cited passages of each document in the ISR will be considered.

**2) Novelty and inventive step according to Art. 33(2) and 33(3) PCT**

The subject-matter of claims 1-18 is novel and inventive over D1-D5 because none of the cited prior art describes nor suggests a method or a device for producing products in web form in which a coating mass is first applied onto the surface of a transfer support web, then treated thermically, then an intermediate support material is applied **onto the coating** and finally the composite of intermediate support layer and coating are separated **by means of rolls** from the transfer support web which is performed as an endless loop.

The claimed method and device permit the continuous production of products in web form and the recycling of the transfer support web which is performed as an endless loop.

- 3) According to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D2 is now mentioned in the description (see amended pages 2 and 2a).

DE-A 36 30 603 provides for a flat dosage form, on a carrier material (release film), to be peelable in doses.

5 WO 01/28904 discloses a device for continuously transferring adhesive laminate systems which enables the transfer of adhesive laminate systems from a slow moving dispensing web to a fast moving acceptor web without subjecting the system to tensile stresses.

10 Drug containing film-shaped systems and their advantages are further known from US patent 5,047,244. These systems comprise a double-layered structure of a water swellable layer and a non-water-swellable barrier film. The use of polymers such as polyethylene glycol, the use of colloidal silicon dioxide, of bioadhesive (e.g. carboxy-functional) polymers, but also of polyvinyl alcohol, and of a number of other auxiliary substances is likewise known from the above publication.

15 A preparation suitable for making film-shaped aromatics-containing preparations is described by EP-A 460 588. A composition comprising 20 to 60 weight-% of film former, 2 to 40 weight-% of gel former, 0.1 to 35 weight-% of active substance or aromatic, and a maximum of 40 weight-% of an inert filling agent is regarded as  
20 affording particular advantages. As a gel former, polyvinyl alcohol is mentioned besides other ingredients. However, as it turns out, the gel-forming properties of ~~polyvinyl~~ alcohol are only partially compatible with the film formers mentioned in this written document. A portion of 20 weight-%, and more, of film-former - mostly a ~~sugar~~ derivative, polyethylene glycol, etc. - lead to considerable loss of aroma  
25 occurring already in thin layer drying, which is part of the production process.

30 The films or coatings to which the instant invention is related are based on organic ~~raw~~ materials or on a mix of such substances. These are preferably water-soluble substances. Such organic raw materials include polymers such as polyvinyl alcohol, ~~polyvinyl~~ pyrrolidone, cellulose derivatives, polyvinyl acetate, polyethylene glycol, ~~agar~~, carrageenan, xanthan, gelatine and other water-soluble polymers known to the skilled artisan, as well as mixtures and copolymers of such substances. If

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desired, such films or coatings may also include fillers such as mannitol, lactose, calcium phosphate, glucose, sorbitol etc., active substances such as drugs, aroma substances, menthol etc., sweeteners such as cyclamate, flavours such as glutamate, and other ingredients, including in some cases volatile ingredients.

5 These films may also have mucoadhesive properties.

## Patent Claims

1. Method for producing products in web form in which a coating mass first is  
applied onto the surface of a transfer support web, subsequently the  
composite of transfer support web and coating is treated thermally, then an  
intermediate support material is applied on the coating and finally the  
composite of intermediate support layer and coating separated from the  
transfer support web by means of rolls, wound up and stored, wherein the  
transfer support web used is performed as an endless loop.
2. Method according to claim 1, wherein the transfer support web is comprised  
of a solid material such as polymer material or of a composite material of  
paper with a polymer layer on top or a metal foil or a composite material of  
metal and polymer film such as metallized polymer film.
3. Method according to claim 1, wherein the endless loop used as the transfer  
support web has a uniform thickness over its total length.
4. Method according to claim 1 wherein the coating is prepared by mixing its  
ingredients in an aqueous medium.
5. Method according to claim 1, wherein the coating is applied to the transfer  
support web in a coating station by a casting method or a reverse coating  
method in a thickness in the range of from 10 to 500  $\mu\text{m}$ , preferably from 50  
to 200  $\mu\text{m}$ .
6. Method according to claim 1, wherein the transfer support web and the  
coating is thermally treated in a heating device.
7. Method according to claim 6, wherein the thermal treatment is performed in  
a hot air chamber at temperatures in the range of from 40 to 120  $^{\circ}\text{C}$ .



16. Method according to claim 1, wherein the regenerated transfer support web is first wound up and after storage recirculated again to the coating station, to be applied again with the coating.

5 17. Device for performing the method for producing products in web form comprising at least a coating station (1), wherein a coating is applied, a laminating- or cooling station (3), a station wherein an intermediate support web (8) is applied onto the coating, separating rolls (4, 5, 6, 7) and a regeneration station (9) for a transfer support web, whereby the transfer support web is performed as an endless coil.

10 18. Device according to claim 17 comprising additionally a heating device (2) between the coating station (1) and the laminating- or cooling station (3).

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